

In re Patent Application of:
Hans Henrik IPSEN, et al.

Filed: November 20, 2003

Art Unit: 1644

For: NOVEL RECOMBINANT ALLERGENS

Examiner: P. Huynh

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

March 12, 2004

Dear Sir:
Sir:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed:

(Check one of the boxes A-D)

- ☐ A. Within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.
- ☒ B. before the mailing date of a first office action on the merits, or a first office action after filing a request for continued examination.
- ☐ C. after (A) and (B) above, but before the mailing date of a final rejection, a notice of allowance, or any other action that closes prosecution, and Applicants have made the necessary statement in box "i" below or paid the necessary fee in box "ii" below.

(check one of the boxes “i” and “ii” below:)

- ☐ i. Counsel states that, upon information and belief, each item of information listed herein was either (a) cited in a communication from a foreign patent

office in a counterpart foreign application not more than three months prior to the filing of this IDS; or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

- ☐ ii. A check for the fee set forth in 1. 17(p), presently believed to be \$180, is enclosed.
- ☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Counsel states that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the IDS; or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- ☐ i. A check for the fee set forth in 1.17 (p), presently believed to be \$180, is enclosed.

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO/SB/08) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A, B and/or C and fill in blanks, if appropriate.)

- ☐ A. Pursuant to the Notice issued by the United States Patent and Trademark Office dated July 11, 2003 waiving the requirements of 37 C.F.R. § 1.98(a)(2)(i), a copy/copies of the United States Patent on PTO/SB08 is/are not being submitted.
- ☐ B. Document(s) _____ is (are) deemed substantially cumulative to document(s) _____, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.
- ☒ C. Documents 1-43 on the attached PTO/SB/08 were previously cited by or submitted to the Office in the following prior applications, which are relied upon under 35 U.S.C. 120:

Serial No. 09/270,910, filed March 16, 1999.

Copies of these documents need not be filed in this application. Applicant requests that these documents be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d).

☐ 3. Document(s) _____ are not in the English language. In accordance with 1.98(c), Applicant states:

- ☐ An English translation of each document (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application is enclosed.
- ☐ A concise explanation of the relevance of document(s) _____ is found in the attached search report (see MPEP 609 A(3)x).
- ☐ A concise explanation of the relevance of document(s) _____ is set forth as follows: [Insert concise explanation of relevance]
- ☐ A concise explanation of the relevance of document(s) _____ can be found on page(s) _____ of the specification.
- ☐ A concise explanation of document(s) _____ can be found on the attached sheet.

4. No explanation of relevance is necessary for documents in the English language (see MPEP ' 609 A(3)).

☐ 5. Other information being provided for the examiner's consideration follows:

6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in 1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless other-wise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

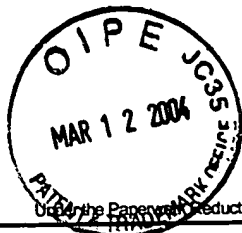
Early and favorable consideration is earnestly solicited.

Respectfully submitted,



Mitchell Bernstein, Ph.D.
Registration No. 46,550
Agent for Applicant(s)

DARBY & DARBY P.C.
805 Third Avenue
New York, N.Y. 10022
(212) 527-7700



PTO/SB/08a/b (06-03)
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Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/719,553
				Filing Date	November 20, 2003
				First Named Inventor	Hans Henrik IPSEN
				Art Unit	1644
				Examiner Name	P. Huynh
Sheet	1	of	3	Attorney Docket Number	04305/100E144-US2

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ³
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	1.	WO 90/11293	10/04/1990	Immulogic Pharmaceutical Corporation		
	2.	WO 92/02621	02/20/1992	Biomay Biotechnik Produktions Und Handelsgesellschaft M.B.H.		
	3.	WO 97/30150	08/21/1997	Pangenetics B.V.		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials ¹	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	4.	Takai T., Yokota T., Yasue M., Nishiyama C., Yuuki T., Mori A., Okudaira H., Okumura Y.: "Engineering of the Major House Dust Mite Allergen Der f 2 For Allergen-Specific Immunotherapy," <i>Nat. Biotechnol.</i> 15: 754-758 (1997).	
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	7.	Forster E., Dudler T., Gmachl M., Aberer W., Urbanek R., Suter M.: "Natural and Recombinant Enzymatically Active or Inactive Bee Venom Phospholipase A2 Has The Same Potency to Release Histamine from Basophils in Patients with Hymenoptera Allergy," <i>J. Allergy Clin. Immunol.</i> 95: 1229-1235 (1995).	
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	9.	Stanley J.S., King N., Burks A.W., Huang S.K., Sampson H., Cockrell G., Helm R.M., West C.M., Bannon G.A.: "Identification and Mutational Analysis of the Immunodominant IgE Binding Epitopes of the Major Peanut Allergen Ara h 2," <i>Arch. Biochem. Biophys</i> 342: 244-253 (1997).	
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Examiner Signature		Date Considered	
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Sheet	2	of	3	Attorney Docket Number	04305/100E144-US2

11.	Ferreira G., Ebner C., Kramer B., Casari G., Briza P., Kungl A.J., Grimm R., Jah-Schmid B., Breiteneder H., Kraft D., Breitenbach M., Rheinberger H.J., Scheiner O., "Modulation of IgE Reactivity of Allergens by Site-directed Mutagenesis: "Potential Use of Hypeallergenic Variants for Immunotherapy," <i>FASEB Journal for Experimental Biology</i> , Vol. 12, No. 2: 231-242 (February 1998).		
12.	Wiedemann P., Giehl K., Almo S.C., Federov A.A., Girvin M., Steinberger P., Rudiger M., Ortner M., Sippl M., Dolecek C., Kraft D., Jockusch B., Valenta R.: "Molecular and Structural Analysis of a Continuous Birch Profilin Epitope Defined by a Monoclonal Antibody," <i>J. Biol. Chem.</i> 271, 29915-29921 (1996).		
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14.	Colombo P., Kennedy D., Ramsdale T., Costa M.A., Djro G., Izzo V., Salvadori S., Guerrini R., Cocchiara R., Mirisola M.G., Wood S., Geraci D.: "Identification of an Immunodominant IgE Epitope of the Parietaria judaica Major Allergen", <i>Journal of Immunology</i> , Vol. 160, No. 6: 2780-2875 (15 March 1998).		
15.	Spangfort M.D., Ipsen H., Sparholt S.H., Aasmul-Olsen S., Larsen M.R., Mortz E., Roepstorff P., Larsen J.N.: "Characterization of Purified Recombinant Bet v 1 With Authentic N-terminus, Cloned in Fusion with Maltose-Binding Protein," <i>Prot. Exp. Purification</i> 8L 365-373 (1996).		
16.	Ipsen H., Wihl J.A., Petersen B.N., Lowenstein H.: "Specificity Mapping of Patients IgE Response Towards the Tree Pollen Major Allergens Aln g I, Bet v I and Cor a I," <i>Clin. Exp. Allergy</i> 22: 391-9 (1992).		
17.	Gajhede M., Osmark P., Poulsen F.M., Ipsen H., Larsen J.N., Joost van Neerven R.J., Schou C., Lowenstein H. and Spangfort M.D.: "X-ray and NMR Structure of Bet v 1, the Origin of Birch Pollen Allergy," <i>Nature Structural Biology</i> 3: 1040-1045 (1996).		
18.	Altschul S.F., Gish W., Miller W., Myers E.W., and Lipman D.J.: "Basic Local Alignment Search Tool," <i>J. Mol. Biol.</i> 215: 403-410 (1990).		
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22.	Monsalve R.I., Lu G., and King T.P.: "Recombinant Venom Allergen, Antigen 5 of Yellowjacket (<i>Vespa Vulgaris</i>) and Paper Wasp (<i>Polistes Annularis</i>) by Expression in Bacteria or Yeast" (1999).		
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Examiner Signature		Date Considered	

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		Examiner Name	P. Huynh		
Sheet	3	of	3	Attorney Docket Number	04305/100E144-US2

25.	In-Cheol Kang et al., "Purification and Molecular Cloning of a Platelet Aggregation Inhibitor from the Snake (Agkistrodon Halys Brevicaudus) Venom," <i>Thrombosis Research</i> 91: 65-73 (1999).
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29.	Stefan Niewiarowski et al., Disintegrins and Other Naturally Occurring Antagonists of Platelet Fibrinogen Receptors, <i>Seminars in Hematology</i> 31(4): 289-300 (1994).
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33.	Judah Folkman et al., "Blood Vessel Formation: What Is Its Molecular Basis?" <i>Cell</i> 87(27): 1153-1155 (1996).
34.	Peter C. Brooks et al., "Integrin $\alpha v \beta 3$ Antagonists Promote Tumor Regression by Inducing Apoptosis of Angiogenic Blood Vessels," <i>Cell</i> 79(30): 1157-1164 (1994).
35.	Richard O. Hynes, "Integrins: A Family of Cell Surface Receptors," <i>Cell</i> 48(27): 549-554 (1987).
36.	Hannu Larjava et al., "Novel Function for $\beta 1$ Integrin in Keratinocyte Cell-Cell Interaction," <i>J. Cell Biol.</i> 110: 803-815 (1990).
37.	Erkki Ruoslahti, "How Cancer Spreads," <i>Scientific American</i> : 73-77 (September 1996).
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40.	Skolnick et al., "From genes to protein structure and function: novel applications of computational approaches in the genomic era," <i>Trends in Biotech</i> 18(1): 34-39 (Jan. 2000).
41.	Attwood et al., "The babel of bioinformatics," <i>Science</i> 290 (5491): 471-473 (Oct. 2000).
42.	Lederman et al., "A Single Amino Acid Substitution in a Common African Allele of the CD4 Molecule Ablates Binding of the Monoclonal Antibody, OKT4," <i>Molecular Immunology</i> 28(11): 1171-81 (1991).
43.	Abaza et al., "J. of Protein Chemistry 11(5): 433-444 (1992).

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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03-1584

PTO/SB/92 (08-03)

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Application No. (if known): 10/719,553

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